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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALLAN M. TEREBA, REX M. BITNER, SUSAN C. KOLLER,
CRAIG E. SMITH, DANIEL D. KEPHART, and STEVEN J. EKENBERG

Appeal 2010-008240
Application 10/694,475
Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Representative Claims

44. A method for isolating a defined and consistent amount of DNA from multiple samples comprising:
- (a) selecting a defined amount of DNA to be isolated from the samples;
 - (b) choosing a discrete amount of a silica-containing solid support necessary to isolate the defined amount of DNA from each sample;
 - (c) contacting each sample with the discrete amount of the silica-containing solid support, each sample comprising DNA in excess of the binding capacity of the discrete amount of silica-containing solid support, under conditions that allow reversible binding of the defined amount of DNA to the solid support; and
 - (d) separating each sample from the support to isolate a defined and consistent amount of DNA from each sample.
66. A method of isolating DNA from multiple samples for use in a molecular biological procedure comprising:
- (a) selecting a defined amount of DNA to be isolated from the samples;
 - (b) choosing a discrete amount of a silica-containing solid support necessary to isolate the defined amount of DNA from each sample;
 - (c) contacting each sample with a discrete amount of a silica-containing solid support, each sample comprising DNA in excess of the binding capacity of the discrete amount of silica-containing solid support, under conditions that allow reversible binding of the defined amount of DNA to the solid support; and
 - (d) eluting bound DNA of step (c) to isolate a defined and consistent amount of DNA from each sample, wherein the eluted DNA is suitable for use in the molecular biological procedure.

Cited References

The Examiner relies on the following prior art references:

Melzak et al., *Driving Forces for DNA Adsorption to Silica in Perchlorate Solutions*, 181 Journal of Colloid and Interface Science 635-644 (1996).

Kleiber et al. WO96/41811 Dec. 27, 1996

Ryder et al. US 5,639,599 Jun. 17, 1997

PUC18 nucleotide sequence downloaded from

http://seq.yeastgenome.org/vectordb/vector_descrip/COMPLETE/PUC18.SEQ.html - printed 11/13/2008.

Grounds of Rejection

1. Claims 44, 45, 50, 53, 65-66, 67 and 82 are rejected under 35 U.S.C. §102(b) for anticipation over Melzak as evidenced by PUC18.
2. Claims 44, 45, 50, 53, 65-66, 67, 82 and 46-49, 51-52, 54, 58, 60-64, 68, 77-81 are rejected under 35 U.S.C. §103(a) for obviousness over Melzak in view of Kleiber.
3. Claims 69-70, 72-76 are rejected under 35 U.S.C. § 103(a) for obviousness over Melzak in view of Kleiber and Ryder.

FINDINGS OF FACT

The findings of fact are set forth in the Answer at pages 3-10 and are characterized as set forth below.

1. The Examiner finds that step (a) of claim 44, “selecting a defined amount of DNA to be isolated from the samples”, is disclosed in the closed circle data points in Fig. 3(b) of Melzak which represent a defined amount of DNA isolated from the samples (*see* Ans. 5). In particular, *see* Fig. 3(b) x axis.

2. The Examiner finds that step (b) of claim 44, “choosing a discrete amount of a silica-containing solid support necessary to isolate the defined amount of DNA from each sample”, is disclosed in Melzak at page 637, fourth paragraph. Here Melzak discloses measuring a silica surface area of $5.6 (\pm 0.2) \text{ m}^2/\text{g}$ with a saturation of $380 \text{ } \mu\text{g DNA per m}^2$ on the silica as in Fig. 3b.
3. The Examiner finds that step (c) of claim 44, “contacting each sample with the discrete amount of the silica-containing solid support, each sample comprising DNA in excess of the binding capacity of the discrete amount of silica-containing solid support, under conditions that allow reversible binding of the defined amount of DNA to the solid support”, is disclosed at Melzak Fig. 3(b) where past the saturation point, “DNA samples are introduced to the silica in excess of the silica binding capacity” (Ans. 5). Reversible DNA binding is disclosed at Melzak, page 639, col. 2.
4. The Examiner finds step (d) of claim 44, “separating each sample from the support to isolate a defined and consistent amount of DNA from each sample”, is disclosed in the quantitative DNA reversible absorption step. (See Melzak, page 639, col. 2.)
5. The Examiner finds that multiple DNA samples are tested in Melzak including plasmid pUC18 and salmon sperm DNA. (Melzak, page 639, col.1.)

Discussion

ISSUE

The Examiner concludes that Melzak teaches each element claimed.

Appellants argue that Melzak “fails to teach or suggest all of the claim limitations” (App. Br. 12). In particular, Appellants argue that Melzak fails to disclose steps “(a) selecting a defined amount of DNA to be isolated from the samples;’ and ‘(b) choosing a discrete amount of a silica-containing solid support necessary to isolate the defined amount of DNA from each sample.’” (*Id.*)

The issue is: Do the cited prior art references teach each step of the invention, as claimed?

PRINCIPLES OF LAW

“Without evidence in the patent specification of an express intent to impart a novel meaning to a claim term, the term takes on its ordinary meaning.” *Optical Disc Corp. v. Del Mar Avionics*, 208 F.3d 1324, 1334 (Fed. Cir. 2000).

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citations omitted). In order to determine whether a *prima facie* case of obviousness has been established, we consider the factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at

issue; (3) the level of ordinary skill in the relevant art; and (4) objective evidence of nonobviousness, if present.

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

“[W]hen a *prima facie* case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability.” *In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002). Rebuttal evidence is “merely ‘a showing of facts supporting the opposite conclusion’”. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539 (CCPA 1967) (“Since the alleged problem in this case was first recognized by appellants, and others apparently have not yet become aware of its existence, it goes without saying that there could not possibly be any evidence of either a long felt need in the . . . art for a solution to a problem of dubious existence or failure of others skilled in the art who unsuccessfully attempted to solve a problem of which they were not aware.”); *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376 (Fed. Cir. 1983) (Although the claimed invention achieved the desirable result of reducing inventories, there was no evidence of any prior unsuccessful attempts to do so.).

Second, the long-felt need must not have been satisfied by another before the invention by applicant. *See Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988) (Although at one time there was a long-felt need for a “do- it-yourself” window shade material which was adjustable without the use of tools, a prior art product fulfilled the need by using a scored plastic material which could be torn.)

“[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved”. *Id.*

Third, the invention must in fact satisfy the long-felt need. *See In re Cavanagh*, 436 F.2d 491 (CCPA 1971). Manual of Patent Examining Procedure § 716.04.

ANALYSIS

We agree with the Examiner’s fact finding, statement of the rejection and responses to Appellants’ arguments as set forth in the Answer and find that the Examiner has presented a prima facie case of anticipation. We provide the following additional comment.

Appellants argue that Melzak fails to disclose steps ““(a) selecting a defined amount of DNA to be isolated from the samples;”, and ““(b) choosing a discrete amount of a silica-containing solid support necessary to isolate the defined amount of DNA from each sample.”” (App. Br. 12.) Appellants argue that Melzak “varied the dilution of DNA in the samples merely to illustrate that the amount of DNA in the sample had no impact on whether the binding was reversible.” (*Id.*)

Appellants do not define in the Specification what is meant by the phrase “selecting a defined amount of DNA to be isolated from the

samples”. (Claims 44 and 66.) Thus we give the phrase its ordinary meaning of choosing an amount of DNA to be tested. Melzak discloses such a step in Fig. 3b. (FF1.)

The burden of proof thus shifted to Appellants to rebut the disclosure of Fig. 3b of Melzak. Appellants provide no evidence to show that Melzak Fig. 3b does not disclose a step of selecting an amount of DNA and thus do not rebut the prima facie case of the Examiner. While Appellants argue that Melzak varied the amount of DNA for another reason, Melzak, notwithstanding, discloses a step of selecting a defined amount of DNA, as claimed.

Appellants further argue that Melzak does not disclose claimed step b, “choosing a discrete amount of a silica-containing solid support necessary to isolate the defined amount of DNA from each sample.” (App. Br. 12.)

Melzak discloses measuring a silica surface area of $5.6 (\pm 0.2) \text{ m}^2/\text{g}$ with a saturation of $380 \text{ } \mu\text{g DNA per m}^2$ on the silica as in Fig. 3b. (FF2.) The burden of proof thus shifted to Appellants to rebut the disclosure of Fig. 3b of Melzak. Appellants provide no evidence to show that Melzak Fig. 3b does not disclose a step choosing a discrete amount of a silica-containing solid support necessary to isolate the defined amount of DNA from each sample and thus do not rebut the prima facie case of the Examiner.

The anticipation rejection is affirmed.

2. Claims 44, 45, 50, 53, 65-66, 67, 82 and 46-49, 51-52, 54, 58, 60-64, 68, 77-81 are rejected under 35 U.S.C. § 103(a) for obviousness over Melzak in view of Kleiber.

3. Claims 69-70, 72-76 are rejected under 35 U.S.C. § 103(a) for obviousness over Melzak in view of Kleiber and Ryder.

ISSUE

The Examiner argues that any deficiencies of Melzak as to the subject matter of the dependent claims are met by the disclosure of Kleiber.

Appellants argue, similar to the anticipation rejection, that Melzak does not teach claim steps a and b. (*See* App. Br. 14.) Appellants further argue that Kleiber does not disclose or “suggest the problem of isolating defined and consistent amounts of DNA from multiple samples” or “selecting a defined amount of DNA... and choosing a discrete amount of silica”(*id.*).

Does the combination of Melzak and Kleiber disclose the method as claimed?

ANALYSIS

We select claims 44 and 66 as representative claims as Appellants have not separately argued individual claims. Appellants argue that Melzak does not disclose claim 44 steps a and b. For the reasons discussed above with respect to the anticipation rejection, we do not find that Appellants have provided evidence to rebut the *prima facie* case established by the Examiner with respect to Melzak.

Appellants further argue that Kleiber does not disclose or suggest the problem of isolating defined and consistent amounts of DNA from multiple samples or selecting a defined amount of DNA and choosing a discrete amount of silica. Thus Appellants essentially argue the Kleiber does not make up for the deficiencies of Melzak. Having found no deficiency in

Melzak, we find the Examiner has established a prima facie case of obviousness.

Appellants rely on the Declaration of Bitner¹ as evidence of non-obviousness of the claimed invention. However, the Bitner Declaration does not address the disclosure and teachings of Melzak. Appellants rely on the Declaration of Bitner as evidence of “contemporaneous appreciation” of the invention by those skilled in the art. (*See* Reply Br. 11.) We agree with the Examiner that the Declaration of Bitner does not show that the “claimed features were responsible” for the praise received by the method (Ans. 13), since the basis for receiving the R & D 100 Award is unstated. Also, praise for the invention appears to be directed to “providing a solution to the problem of being able to isolate a defined and consistent amount of DNA from multiple samples” (App. Br. 15), a feature that was already described by Melzak, as discussed above regarding the anticipation rejection. As the Federal Circuit has noted, a nexus between a secondary consideration and an invention must be based on a novel feature of the claim. *See In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (“Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention.”).

The Examiner also finds the Declaration insufficient to establish “long felt need” in the art for the invention. (*Id.*) We agree that the Declaration is insufficient to show long-felt need for the reasons indicated by the Examiner in the Answer at page 14.

¹ Declaration of Rex Bitner executed October 30, 2007.

We are aware that the Exhibits attached to the Declaration appear to indicate a significant reduction in the processing time associated with the claimed method. However, the claims fail to recite processing time limitations.

Appellants argue the rejection over Melzak in view of Kleiber and Ryder by again arguing that Melzak fails to disclose claim 44 steps a and b. (*See App. Br. 16.*) Having found no deficiency in Melzak we also affirm this rejection.

CONCLUSION OF LAW

The cited references support the Examiner's obviousness rejection which is not overcome by the Bitner Declaration.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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